

BRS Factsheet

Biotechnology Regulatory Services

U.S. Department of Agriculture
Animal and Plant Health Inspection Service

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BQMS Program Mission

Biotechnology Regulatory Services (BRS) provides support for the voluntary adoption of a BQMS to improve the management of an organization's domestic research and development of regulated GE organisms.

"....We are better organized and equipped to ensure that internal and external associates can perpetuate good practices."

-BQMS Pilot Program Participant



Biotechnology Quality Management System Program

Improving the Management of Regulated Genetically Engineered Organisms

The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) Biotechnology Quality Management System (BQMS) Program provides compliance assistance to the regulated community for the voluntary adoption of a BQMS. A BQMS serves as an important tool to help organizations involved in biotechnology research and development analyze the critical control points within their management system to better maintain compliance with USDA APHIS regulations for the import, interstate movement, and environmental release of regulated genetically engineered (GE) organisms.

As part of the BQMS Program initiative, APHIS launched a pilot project to test the applicability of the BQMS draft audit standard and guidelines. APHIS gathered public feedback to refine the draft audit standard and guidelines in preparation for the Program's full implementation.

A Dynamic, Science-Based Approach

The BQMS integrates a science-based approach of risk assessment and mitigation, allowing for sound decision-

making and effective management of the research and development of regulated GE organisms. The BQMS integrates principles from other quality management systems, such as the Codex Alimentarius Hazard Analysis Critical Control Point System and ISO 9001:2008.

Providing Assistance Every Step of the Way

The APHIS BQMS Program provides participants with the tools and guidance needed to develop a BQMS that is tailored to their organization's needs. Specifically, the Program provides:

- interactive training workshops with other BQMS Program participants and USDA officials,
- documented guidelines and templates to aid in the development of a BQMS,
- a baseline assessment of current management practices in relationship to the BQMS standard,
- one-on-one targeted assistance as needed,
- internal audit training,
- facilitated third-party audits of the organization's BQMS, and

- acknowledgement of BQMS Program completion.

Raising the Bar

Although the Program provides support, it places ownership and responsibility on the participating organization to control identified risks to the confinement, containment, and identity of regulated GE organisms. This ownership enables researchers to document the effectiveness of their management systems for regulated GE imports, interstate movements, and environmental releases. It also requires continuous self-monitoring and verification to demonstrate that the system is working and to reveal when potential regulatory noncompliance incidents have occurred.

Expect a Difference

Participants will develop, implement, and maintain a BQMS within their organization to manage the movement and field release of regulated GE organisms. Specifically, organizations will:

- work to identify critical control points in the organization's processes for working with regulated GE organisms,

Get the BQMS Advantage

- Document and Record Control
- Effective Training
- Continuous Improvement

“Participation really helped us understand the value of quality management systems in biotechnology [research and development], because it brings good management practices to the organization in conducting the regulated field trials.”

- BQMS Pilot Program Participant

- develop or revise standard operating procedures that address critical control points,
- properly train personnel on the standard operating procedures,
- undergo a third-party audit to determine effectiveness of the organization’s quality management system, and
- become an organization recognized as completing the BQMS Program.

To learn more about the APHIS BQMS Program and how you can participate, go to:

www.aphis.usda.gov/biotechnology/news_bqms

To contact a BQMS Program representative, e-mail or call us at
BRS.BQMS@aphis.usda.gov or
(301) 734-6356.

USDA is an equal opportunity provider and employer.

Get Started Today

The APHIS BQMS Program is available to interested parties in the regulated community who wish to validate their approach to APHIS regulatory compliance. Participation is limited based on available resources. Please visit www.aphis.usda.gov/biotechnology/news_bqms.shtml for a list of tentative training dates.

